REMARKS

Claims 18, 20, 23-26 and 31-35 are pending in this application. By this Amendment, claims 18, 20, 34 and 35 are amended. No new matter is added.

Personal Interview

Applicant thanks the Examiner for the courtesies extended during an August 11, 2003, personal interview with Applicant's representatives during which the outstanding rejections of record were discussed. The remainder of Applicant's separate record of the interview is contained in the remarks below.

Section 112 Rejection

The Office Action rejects claims 34 and 35 under 35 U.S.C. § 112, first paragraph, as not being sufficiently described in the specification. In particular, the Patent Office asserts that the specification does not provide support for a method wherein "the treatment period is 3 to 6 weeks." As was agreed during the personal interview, amending claims 34 and 35 to recite "at least 3 weeks" is supported by the specification. Applicants have amended claims 34 and 35 accordingly.

Reconsideration and withdrawal of the rejection of claims 34 and 35 under 35 U.S.C. § 112, first paragraph, are thus respectfully requested.

Section 102/103 Rejections

The Office Action rejects claims 18, 20, 23-26 and 32-33 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over

Toshihide et al. and over Pettersson et al. Toshihide et al. These rejections are traversed as they may apply to the amended claims.

The present invention relates to the new use of EPO for alleviating the disease activity of chronic inflammation in general and rheumatoid arthritis in particular. The disease activity of rheumatoid arthritis (RA) is for example assessed by determining grip strength, number of swollen or painful joints, morning stiffness or pain score.

Pettersson et al. describe a 24-week open clinical study in which 12 patients with RA and anemia were treated with EPO. One patient discontinued treatment with EPO because of moving abroad. The results of this patient are not included in the statistical calculations (see page 190, right column, fourth paragraph). Hence, 11 patients completed the study. Furthermore, it is disclosed on page 190, right column, first paragraph that "Ten patients received oral iron supplementation for at least 20 out of the 24 weeks of treatment with rHuEPO."

It is clear from the patent application that (page 4, lines 6 to 15) "Iron (free and/or bound in ferritin) deposits are known to occur in the synovia of Ra-affected patients. Synovial fluid iron levels correlate with RA activity and therefore it is thought that iron is involved in the initiation or maintenance of RA synovitis through mediating tissue damage.

The role of iron in the pathogenesis of RA may be related to the fact that iron stimulates the production of hydroxyl radicals, which are potent agents in the destruction of cartilage, membranes and proteins."

Hence, this leads to the following conclusions: (i) the steps as outlined in Pettersson et al. are not identical to the steps in the present claims (no iron supplementation) and (ii) it is clear that Pettersson came to the conclusion that *"there was*

no significant change in our patients' joint status or in their ESR and CRP values..." (see page 192, left column, second paragraph), because the supplementation of free iron has a negative effect on the RA disease related symptoms.

The Office Action asserts that present claims "recite no limitation that would exclude oral iron supplementation...[and] the use of the term 'comprising' in the claimed method indicates that the claimed method encompasses any method comprising any additional steps or supplemental reagents" (see lines 15-20 on page 4 of the Office Action).

In order to expedite prosecution of this application, Applicant has amended the claims to use the term 'consisting of' thus excluding from the claimed invention a method that includes additional supplemental reagents such as the iron of Pettersson et al.

Hence, Pettersson et al. clearly do not disclose the method as claimed. Furthermore, because Petersson et al. do not suggest omitting the supplementation of iron, the claims would not have been obvious.

Toshihide et al. disclose the use of EPO during 2 or 3 weeks for increasing erythropoiesis in RA patients. However, it is disclosed that during this treatment period 800 or 1200 ml of blood was collected from said patients; this step is not performed in the presently claimed method.

The Office Action asserts that "the instant claims recite no limitation that would exclude the collection of blood...[and] the use of the term 'comprising' in the claimed method indicates that the claimed method encompasses any method comprising any additional steps or supplemental reagents" (see lines 7-11 on page 3 of the Office Action).

As discussed above for the rejection based on Pettersson et al., in order to expedite prosecution of this application, Applicant has amended the claims to use the term

'consisting of' thus excluding from the claimed invention a method that includes additional supplemental steps such as the Toshihide et al. collection of blood.

Hence, Toshihide et al. clearly do not disclose the method as claimed. Furthermore, because Toshihide et al. do not suggest omitting the collection of blood, the claims would not have been obvious.

For at least the above reasons, reconsideration and withdrawal of the rejections of claims 18, 20, 23-26 and 32-33 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Toshihide et al. and over Pettersson et al.

Conclusion

Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance is earnestly solicited.

Should the Examiner believe anything further is necessary in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's representative at the telephone number listed below.

In the event this paper is not being timely filed, Applicant respectfully petitions for an appropriate extension of time. Any additional fees may be charged to Counsel's Deposit Account 01-2300, **referring to client-matter number 108214-07002.**

Respectfully submitted,

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